The New Hampshire Department of Health and Human Services
Continuing Review and Termination Form

Principal Investigator: _____CPHS #_____

Study Title: _____

Date Study Began: _____

Dartmouth College Affiliated? ☐ No or ☐ Yes (If yes, please submit 2 copies of all materials)

Study Status (check one)

☐ The project did not start and is no longer in operation. - Skip all questions below. Sign and date the form and return it to the CPHS. Please include a copy of the lay summary protocol and a brief description of the circumstances which precluded this study from beginning.

☐ The project did not start but is expected to start during the next year. – Please complete the rest of the form. Sign and date the form and return it to the CPHS. In the progress report section, please describe the circumstances leading to this project not starting or being delayed. Please include:

- A Human Subject Review Form (for studies that do not qualify for expedited review);
- A CPHS stamped copy of the consent;
- A clean copy of the consent form;
- The sponsor protocol or NIH grant application (if applicable); and
- A copy of the Summary protocol.

☐ The project is ongoing. - Please complete the rest of the form, sign and date it and return to the CPHS. Please include:

- A Human Subject Review Form (for studies that do not qualify for expedited review);
- A CPHS stamped copy of the consent;
- A clean copy of the consent form;
- The sponsor protocol or NIH grant application (if applicable); and
- A copy of the Summary protocol.
- Data Safety and Monitoring Board Summary

☐ The project is ongoing but closed to enrollment. - Please complete the rest of the form, sign and date it and return to the CPHS. Please include:

- A Human Subject Review Form (for studies that do not qualify for expedited review)
- The sponsor protocol or NIH grant application (if applicable),
- A copy of the Summary protocol.
- Data Safety and Monitoring Board Summary

☐ The project concluded during the past year. Please complete the remainder of the form, indicating the date of completion below. Sign and date the form and return to the CPHS. Please include:

- A Human Subject Review Form (for studies that do not qualify for expedited review);
- A summary of the results;
- The sponsor protocol or NIH grant application (if applicable); and
- A copy of the Summary protocol.
- Data Safety and Monitoring Board Summary

Date of completion: _____

Annual Review

1. During the past year (since last review) _____ human subjects were studied.

1A. Since the start of the study, how many individuals consented to participate? 0

1B. How many human subjects are currently participating in the study at this time? _____

1C. How many subjects have completed the study? _____

1D. How many subjects have dropped out for the following reasons:

serious adverse event _____ (explain in item 4) lost to follow-up _____ withdrew consent _____

did not adhere to protocol _____ other (please explain below) _____

Note: The number in 1A must equal the sum of 1B + 1C + 1D

2. How much longer is the project likely to continue? _____ years _____ months

3. Progress Report: Summarize the essential aspects of progress or results to date. You may enclose an abstract or other report. **If the study is concluding, please provide a summary of the results.**

4. Were there any SAEs to subjects during the course of this study during the past year (since last review)? If so, describe relatedness to study? Include Incident Reports that have been filed with study sponsors.
Select one: ☐ No ☐ Yes (explain)

5. Were there any unanticipated problems involving risk to subjects or others?
Select one: ☐ No ☐ Yes (explain)

6. Has there been any new information that changes our knowledge of the risks and that could influence a participant's decision to stay with or withdraw from this study? (If yes, please explain)
Select one: ☐ No ☐ Yes (explain)

7. Were any grievances or complaints received about this study?
Select one: ☐ No ☐ Yes (explain)

8. Were any eligibility or protocol deviations reported to the CPHS office?
Select one: ☐ No ☐ Yes (explain)

9. Have any changes occurred that affect the PI or other study personnel's potential for conflict of interest?
Select one: ☐ No ☐ Yes (explain)

10. Summarize revisions **previously reviewed and approved** by the CPHS:

11. Summarize revisions **not yet approved** by the CPHS. **Check all that apply:**
- ☐ These revisions do not increase risks to participants enrolled in the study
- ☐ These revisions do increase risks to participants enrolled in the study. If this item is checked, the department chairperson or equivalent supervisor must sign the form.
- ☐ Revision to currently approved protocol. New version date: _____
- ☐ Revision to currently approved consent
- ☐ Other revision or addition (e.g. advertisement, questionnaire). **Describe**

12. Is there a record of the names of all clients who participated in this study?
Select one: No/Yes
If Yes, where is the record kept and how is it secured?

13. Additional comments?

Signature of PI: _____ Date: _____

Signature of department chair or supervisor: _____ Date: _____
(Only required if changes to study increase risks)

If applicable please include:
- **Progress/Summary report submitted to sponsor**
- **Data and safety monitoring report (clinical trials)**

Print Form Before Closing